II. REMARKS

Preliminary Remarks

Claims 38 and 51 are currently amended. Upon entry of the amendment, claims 38, 39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 will be pending in this application.

Independent claims 38 and 51 are amended to specify that the dosage regimen of the LHRH antagonist is selected so that it suppress endogenous LH secretion, but does not suppress endogenous FSH secretion, which is maintained at a natural level. The support for this amendment is in original claim 1 as filed, page 10 of the specification and Figure 1.

The applicant does not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserves the right to pursue such subject matter in continuing and/or divisional applications.

Reconsideration and allowance of the present application based on the above-described amendments and the following remarks are respectfully requested.

Patentability Remarks

35 U.S.C. §102(b)

Diedrich *et al.*

Claims 38, 39, 42, 44-46, 48-53, 56-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich *et al.* (Hum Reprod. 1994). Diedrich *et al.* describe a method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising (a) administering HMG to induce follicle growth, and (b) administering cetrorelix in a dosage regimen of multiple daily doses of 3 mg/day to prevent a premature LH surge, wherein the first daily dose of cetrorelix was administered on day 7 of the cycle, and daily treatment continued until ovulation was induced by administration of HCG when the leading follicle reached a diameter of 18-20 mm and plasma estradiol levels were > 300 pg/ml per follicle of ≥ 15 mm in diameter. Diedrich *et al.* also describe performing the same method wherein cetrorelix is

administered in a dosage regimen of multiple daily doses of 1 mg/day. *See* page 788, left column, and page 789, paragraph 2 of Materials and methods. As shown in Figures 1 and 2 on page 789, daily doses of cetrorelix were administered from day 7 until ovulation was induced on day 14 or day 15 of the cycle.

The applicants respectfully submit that the claims of the present application are directed to a method that is different from and is not anticipated by the method described by Diedrich *et al.*

As stated above, to anticipate a claim, a reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Citations omitted; *see* above, and Manual for Patent Examining Procedure (M.P.E.P.), §2131.

Pending claims 38, 39, 42, 44-46, 48-53, 56-58 and 60 are not anticipated by Diedrich *et al.*

Independent claims 38 and 51 are amended to be directed to a method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising (a) administering LH and FSH to induce follicle growth, and (b) administering an LHRH antagonist in a single or dual dosage regimen of 3 mg per dose, beginning on cycle day 1 to 10, to prevent a premature LH surge, wherein the dosage regimen is selected to suppress endogenous LH secretion, but does not suppress endogenous FSH secretion, which is maintained at a natural level. **Please note that rejected claims 52, and 53 were previously canceled.**

Diedrich *et al.* describe a method wherein cetrorelix is administered in a dosage regimen of multiple daily doses of 3 mg/day starting on day 7 of the cycle and continuing until ovulation was induced on about day 14 or day 15 of the cycle, in order to prevent a premature LH surge, as discussed above. Diedrich *et al.* do not describe a method comprising administering an LHRH antagonist in a single or dual dosage regimen of 3 mg per dose to prevent a premature LH surge with no effect on FSH levels. The examiner states that the additional limitations recited in the claims would be achieved by the methods taught by Deidrich *et al.* because "they teach the same method steps to the identical patient population. Official Action at page 6. The examiner by this

statement appears to argue that the additional limitations in the claims are inherent to the teachings of Deidrich *et al*. Applicants respectfully disagree.

As stated above, claims 38 and 51 set forth a method wherein the dosage regimen of the LHRH antagonist is selected so that endogenous LH levels are suppressed, but endogenous FSH levels are not. The methods taught by Deidrich *et al.*, 3mg/day, or 1mg/day starting on day 7 and continuing until ovulation, result in suppression of LH levels and FSH levels. Deidrich *et al.*, states, "[t]he suppression of FSH under Cetrorelix treatment was less pronounced, but this might have been due to the longer plasma half-life of the injected FSH." Deidrich *et al.*, at page 790, left column. Moreover, Albano *et al.*, "Hormonal profile during the follicular phase in cycles stimulated with a combination of human menopausal gonadotrophin-releasing hormone antagonist (Cetrorelix)," Human Reproduction, Vol. 11, No. 10, pp. 2214-18 (1996), which teaches a method of administering 0.5mg/day of Cetrorelix starting on day 6 states, "[i]n contrast with other studies, where plasma FSH concentration slightly decreased simultaneously with LH concentration (Deidrich *et al.*, 1994; Olivennes *et al.*, 1994), our study did not reveal a decrease in FSH after the administration of the antagonist (Figure 1)." Albano *et al.*, at page 2116, right column. Additionally, the list of authors on the Albano *et al.* reference include K. Deidrich, the author of the article cited by the examiner and P. Devroey, both of whom are named inventors on the instant application.

The citation to Deidrich *et al.* by Albano *et al.*, is to the reference that the examiner now states inherently teaches a method which would lead to the same results as the presently claimed invention. One of skill in the art at the time of the Albano *et al.* reference, therefore, was aware and understood that the methods taught by Deidrich *et al.* cause a suppression of both LH and FSH. Currently amended claims 38 and 51 encompass a method wherein the endogenous LH level is suppressed, but FSH is not. The methods taught by Deidrich *et al.*, therefore, do not teach every element as set forth in the claim, either expressly or inherently. Accordingly, claims 38 and 51, and pending claims 39, 42, 44-46, 48-50, 56-58 and 60 that depend on claims 38 and 51, are not anticipated by Diedrich *et al.* under 35 U.S.C. §102(b).

In view of the foregoing, withdrawal of the rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. §102(b) as allegedly being anticipated by Diedrich *et al.* is respectfully requested.

Obvious-Type Double Patenting Rejection

Claims 38-39, 42, 45-51, 56-62, 65, 67-74, 78-82, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, 126-128 and 129-141 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of co-pending U.S. Application No. 10/661,780. The claims of Application No. 10/661,780 are directed to a method of treating infertility disorders that comprises inducing follicle growth by administration of hMG or recombinant FSH in combination with clomiphene, which method is considered to be encompassed by the claims of the present application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The examiner states that applicants' request for deferral of the issue submitted in their March 13, 2007 response is not proper. Applicant respectfully disagrees. The examiner is reminded of M.P.E.P. § 804 discussing double patenting and in particular M.P.E.P. § 804 I.B., which states in pertinent part, "[t]he merits of such a provisional rejection **can** be addressed by both the applicant and the examiner without waiting for the first patent to issue." M.P.E.P. § 804 I.B. (emphasis added). There is no requirement that the applicant address the merit of the provisional rejection as applicant can amend claims, or take other action, in either of the two co-pending applications to overcome the rejection. Moreover, the examiner's attention is also drawn to the following statement, "[i]f a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner **should** withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." M.P.E.P. § 804 I.B.1. (emphasis added). Applicant respectfully submits that the rejection under 35 U.S.C. § 102(b) is overcome with the instant amendment to the claims and as the instant application is the earlier filed of the two co-pending applications, respectfully

requests the examiner withdraw the rejection based on nonstatutory obviousness-type double patenting and permit the application to issue as a patent without a terminal disclaimer.

III. CONCLUSION

In view of the foregoing, the applicants believe that the claims are in form for allowance, and hereby respectfully solicit such action. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is strongly urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: November 15, 2007

By: / thomas a cawley jr /
Thomas A. Cawley, Jr., Ph.D.
Registration No.: 40,944
Telephone No.: 703-770-7944

PILLSBURY WINTHROP SHAW PITTMAN LLP
P.O. Box 10500
McLean, VA 22102